

REMARKS

In the Office action of March 25, 2004, claims 1-51 were rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,607,517 ("Dae et al."). Claims 1-13 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,716,386 ("Ward et al."). Claims 1-51 were rejected under 35 U.S.C. 102 as being anticipated by an article entitled "Efficacy of Intraoperative Cooling Methods" by Plattner et al. Claims 51-63 were withdrawn from consideration as being drawn to a non-elected invention.

Claim 29 has been amended to correct an apparent typographical error. Claims 52-63 have been canceled without prejudice. New claims 64-74 have been added. Claims 1-51 and 64-74 are pending and under consideration in the present application. Applicant respectfully requests reconsideration of the present application.

SECTION 102 REJECTION BASED ON THE DAE PATENT

Claims 1-51 were rejected as being anticipated by the Dae `517 patent under 35 U.S.C. 102(e). The Office action asserts that the Dae `517 patent discloses all of the claimed features, including the step of exchanging heat between a balloon catheter and the stomach. Although column 4, lines 23-24 of the Dae `517 patent describes "a heat exchange catheter placed directly within the stomach," this disclosed subject matter was conceived by Paul M. Stull, the named inventor of the present application. This is unequivocally set forth in the Declaration Under 37 CFR § 1.132 by Paul M. Stull which is being submitted concurrently herewith. Because the Rule 132 Declaration establishes that the disclosure in the Dae `517 patent regarding the use of a heat exchange catheter placed directly within the stomach is attributable to the inventor in the present application, the Dae `517 patent is no longer applicable. *See* M.P.E.P. 716.10 ("[A]n affidavit or declaration may be submitted which attempts to attribute an activity, a reference or part of a reference to the applicant. If successful, the activity or the reference is no longer applicable."). Accordingly, Applicant respectfully requests that the Section 102 rejection based on the Dae `517 patent be withdrawn.

SECTION 102 REJECTION BASED ON THE WARD PATENT

Claims 1-13 were rejected as being anticipated by the Ward Patent. The Office action asserts that the Ward patent also discloses the step of exchanging heat between a balloon catheter and the stomach. Applicant respectfully disagrees, and submits that the Ward '386 patent appears to disclose a device for exchanging heat with the esophagus, but not the stomach. Although the Ward patent appears to disclose an "anchoring stomach bladder," this bladder does not appear to perform a heat exchange function. *See* col. 11, lines 27-34; col. 13, lines 24-28; col. 14, lines 43-45; and Figs. 2, 12 and 14. For example, the Ward patent discloses that a stomach bladder is inflated in the stomach to anchor the device in place within the esophagus. As shown in Figure 12, the heat transfer surface 66 is separate from the anchoring stomach bladder 64. *See also* col. 13, lines 24-33. The heat transfer surface 66 is not within the stomach, but within the esophagus. *See* col. 13, lines 31-38.

Applicant respectfully submits that the Ward patent does not disclose the step of exchanging heat between a balloon catheter and the stomach. Applicant respectfully requests that the Section 102 rejection based on the Ward patent also be withdrawn.

SECTION 102 REJECTION BASED ON THE PLATTNER ARTICLE

Claims 1-51 were rejected as being anticipated by an article entitled "Efficacy of Intraoperative Cooling Methods" by Plattner et al. The Office action asserts that the Plattner article discloses all of the claimed features including the step of exchanging heat between a balloon catheter and the stomach. Applicant respectfully disagrees.

The Office action did not specifically identify where the Plattner article disclosed the step of exchanging heat between the balloon catheter and the stomach. Instead, the Office action merely cited the "Entire Article." Applicant respectfully submits that the Plattner article discloses five cooling methods:

- 1) circulating water (5° C, full length mattress and cover);
- 2) forced air (5° C, full length cover);
- 3) gastric lavage (500 ml iced water every 10 minutes)
- 4) bladder lavage (300 ml iced Ringer's solution every 10 minutes)
- 5) ice water immersion.

These methods are discussed in the abstract and on pages 1090 and 1091 of the Plattner article. The Office action did not identify which one of these five methods was being relied upon for the Section 102 rejection. Of these five methods, the gastric lavage method is the only one that makes reference to the stomach. However, none make reference to the use of a balloon catheter in the stomach.

Although the Plattner article discloses the use of gastric lavage, this does not appear to require the use of a balloon in the stomach. Gastric lavage is the washing out of the stomach with fluid. *See, e.g.*, Taber's Cyclopedic Medical Dictionary, ed. 18 (1997) at 777. The fluid irrigates the stomach and is then drained from the stomach. This would appear to require unconstrained fluid, and would not be consistent with the use of a balloon catheter.

The Office action has failed to identify where the Plattner article discloses the use of a balloon catheter, let alone the step of exchanging heat between the balloon catheter and the stomach. Applicant respectfully submits that the Plattner article does not teach the use of a balloon catheter for exchanging heat with the stomach. Applicant respectfully requests that the Section 102 rejection based on the Plattner article be withdrawn.

NEW CLAIMS

Claims 64-74 have been added by the present amendment. Applicant respectfully submits that the new claims are fully supported by the application as originally filed. No new matter has been added.

INFORMATION DISCLOSURE STATEMENT

An Information Disclosure Statement for the present application was submitted on March 18, 2002. Applicant has not yet received an initialed copy of the Information Disclosure Statement. *See* M.P.E.P. 609. Applicant respectfully requests that the references cited in Information Disclosure Statement of March 18, 2002, and the Supplemental Information Disclosure Statement concurrently submitted herewith, be considered by the Examiner. Applicant further requests that both Information Disclosure Statements be initialed with copies thereof sent to Applicant.

CONCLUSION

Applicant respectfully requests favorable reconsideration of the present application at an early date. Should the Examiner have any comments or questions regarding any of the foregoing, kindly telephone the undersigned.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By: _____

James Juo

Registration No. 36,177

Howard Hughes Center
6060 Center Drive, Tenth Floor
Los Angeles, CA 90045
Telephone: (310) 824-5555
Facsimile: (310) 824-9696
Customer No. 24201